REMARKS

This is in response to the Office Action mailed August 18, 2004.

In that Office Action, claims 1-5, 7-10, 25 and 28 were rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point, distinctly claim the subject matter which the Applicant regards as the invention. Specifically, claim 1 was rejected for lacking antecedent support for the term "said blood." Claim 4 was rejected on the grounds that it requires the blood component to be a plasma which cannot be easily separated into a blood component layer and supernatant layer. Further, the Examiner questioned how claims 9 and 10 now fit into the amended process of claim 1.

Claims 1-5, 7-10, 25 and 28 were rejected under 35 USC 103 as being unpatentable over U.S. Patent No. 6,544,727 to Hei or U.S. Patent No. 5,908,742 to Lin et al.

By this Amendment, claims 4, 9 and 10 have been cancelled, thus overcoming the Examiner's rejections under 35 USC §112, second paragraph, relative to these claims.

Claim 1 has been amended in the manner set forth above. Specifically, claim 1, as now amended, recites the steps of providing a container system that contains at least a pre-connected interim container, a container including a liquid synthetic medium and a transfer container where both the medium

container and the transfer container are in openable flow communication with the interim container. The method of claim 1, as amended, further includes providing a source container including a quantity of a blood component derived from an apheresis procedure where the source container is separate from the container system of claim 1.

Next, the method of amended claim 1 includes establishing fluid communication between the source container and the interim container and transferring the apheresis derived blood component to the interim container. The interim container is centrifuged to substantially separate the blood component into the blood component and a supernatant component. The supernatant component is then substantially removed from the interim container and transferred to the empty transfer container. The method further includes determining the amount of the supernatant component remaining with the blood component. The method includes combining a selected quantity of the blood component with a selected quantity of the synthetic medium within the interim container to provide a blood product that has supernatant component and the synthetic medium in a ratio effective for a pathogen inactivation treatment.

Optionally, as set forth in new claims 29 and 30, the method may further include adjusting the amount of supernatant in the interim container after the determining step (claim 29)

and transferring an amount to the supernatant from the transfer container back to the interim container after the determining step (claim 30).

Applicants respectfully submit that the difference between claim 1, as now amended, and the method described in the referenced prior art is not simply in how the platelet concentrate is prepared. In contrast to the methods described in the cited prior art, the present invention provides a method for preparing a pathogen inactivation-ready blood component, such as platelet concentrate, from apheresis platelets and/or platelet concentrates (with some plasma) derived from apheresis systems that do not have the capability of introducing or combining the collected component with the synthetic medium in the desired ratio of media to supernatant.

Whereas certain apheresis systems will have the synthetic storage medium pre-attached to the collection set (such as those offered by the Assignee of the present application), other apheresis collection sets and systems do not have such pre-attached synthetic media. Accordingly, for components collected on these other systems, the collected component (such as platelet concentrate) must be pre-conditioned for pathogen inactivation. Thus, the present system and the method of claim 1 allow users of such other apheresis systems to prepare

pathogen inactivation-ready blood components for treatment in specific pathogen inactivation protocols.

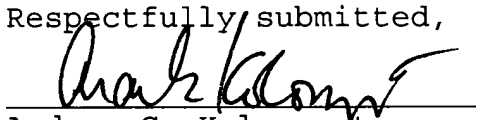
By using the method of claim 1, users of such systems can "convert" their apheresis-derived blood components, such as platelet concentrates, to pathogen inactivation-ready blood components that include pre-selected ratios of the synthetic medium and other components. Providing a system with the specific container arrangement of claim 1 allows users of these systems to remove any necessary amount of supernatant, determine the amount of supernatant required to achieve the pre-selected ratio, add the required amount of the synthetic medium and, if necessary, add back additional supernatant to achieve the desired ratio within an integrated system. Applicants respectfully submit that the container system and method of claim 1 address a need in the blood collection and blood banking field to provide pathogen inactivation-ready blood components obtained from a variety of apheresis systems, but adapted for treatment in a recognized pathogen-inactivation system.

As for the prior art, the methods described in the cited references (Hei and Lin) and specifically the method described with reference to Figures 20a, 20b and 20c (of Hei) describes a system for combining platelet concentrate (apparently collected manually) with a synthetic blood medium. Example 42 of the Hei patent discusses a method for combining the synthetic medium

with the apheresis platelets during the apheresis procedure. However, as described above, the system in Hei Example 42 is different from the apheresis systems (which do not have a means for adding the synthetic media during apheresis) for which the present invention has been developed. In view of these differences and the important need addressed by the method of claim 1, Applicants respectfully submit that claim 1, as amended, and its dependent claims would not have been obvious in view of either U.S. Patent No. 6,544,727 or U.S. Patent No. 5,908,742.

Applicants believe that the claims are now in condition for allowance. Reconsideration and allowance of such claims are respectfully requested.

Respectfully submitted,



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